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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on March 21, 2003, from 8 a.m. to 4:30 p.m.

*Location:* Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

*Contact Person:* Kathleen Reedy or Carolyn Jones, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, or e-mail: REEDYK@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The subcommittee will: (1) Discuss the mission of the subcommittee, (2) discuss the direction of the initiative entitled “Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach” (see the FDA Internet site at <http://www.fda.gov/oc/guidance/gmp.html>), and (3) receive an update on the regulatory approaches regarding aseptic manufacturing.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 7, 2003. Oral presentations from the public will be scheduled between approximately 11:30 a.m. to 12:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 7, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

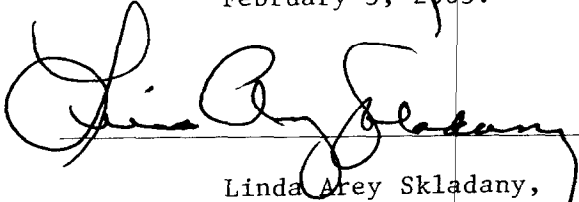
Persons attending FDA’s advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Carolyn Jones at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act  
(5 U.S.C. app. 2).

Dated:

*February 3, 2003*  
February 3, 2003.



Linda Arey Skladany,  
Associate Commissioner for External Relations.

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